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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,038	03/11/2004	Paul T. Gardiner	11411/11502	6719
26646 7590 06/28/2007 KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004				
EXAMINER CHOI, FRANK I				
ART UNIT		PAPER NUMBER		
1616				
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06/28/2007		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/799,038

Applicant(s)

GARDINER ET AL.

Examiner

Frank I. Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 98-111 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 98-111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/15/2007 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 98-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabor (US Pat. 6,482,448) in view of Hastings et al. (US 2001/0041187), Miller et al. (US Pat. 6,019,999), Ostlund et al. (US Pat. 5,550,166) and Shimizu et al. (US Pat. 6,004,926).

Tabor discloses a dietary supplement which comprises a soy formulation and preferably comprising 70-90%, by weight, protein, 1-5%, by weight fat, and 1-25%, carbohydrate which may in the form of a powder or liquid form (Column 6, lines 15-46).

Hastings et al. discloses a performance-enhancing supplement in powder form which can be mixed with uice, water, milk or any other drinkable non-alcoholic beverage with the recommended daily serving being about 26 grams to about 78 grams in the which the major ingredient is soy protein (Paragraphs 0006, 0007). It is disclosed that the supplement contains an amino acid premix of l-leucine, l-glutamine, l-alanine, glycine, l-arginine, l-lysine and that glutamine promotes anabolic conditions in muscle cells, increase rate of protein and glycogen

synthesis, and indirectly promotes muscle growth, that alanine is an important source of energy for muscle tissue and that arginine is essential for optimal muscle growth and tissue repair (Paragraphs 0008-0010). It is disclosed that the supplement contains fat in the form of medium chain triglycerides with improve the absorption of the amino acids (Paragraph 0012) It is disclosed that the dietary supplement should include carbohydrate which supplies an energy source (paragraph 0014). It is disclosed that L-carnitine is added as it has been shown that athletes who supplement their diet with the same convert fat to energy more efficiently (Paragraph 0017). It is disclosed that individuals on an intense physical training regiment will gain optimal results at the higher levels of consumption whereas those on moderate or casual workout regimens will require less (Paragraph 0006).

Miller et al. discloses that for resistance-trained athletes the intake for protein should be approximately twice the normal RDI and that a preferred source of animal protein is dairy whey (column 1, lines 60-68, Column 2, line 1). A liposomal, ion-exchange whey protein is disclosed which is effective in increasing lean body mass, muscle mass with appropriate exercise and improving exercise performance (column 7, lines 46-60).

Ostlund et al. disclose that pinitol and derivatives and metabolites thereof are useful in nutritional composition for treating conditions associated insulin resistance including complications arising from athletic activity (Abstract). It is disclosed that inositol compounds improve insulin sensitivity (Columns 2, 3).

Shimizu et al. disclose a supplement containing protein, fat and carbohydrate which is ingested before, during and/or after exercise, particularly after the exercise immediately preceding a resting period, the protein is selectively taken up in the muscle tissue in the state where the process of protein assimilation is invigorated by the exercise, while the fat is

combused as an energy source and consumed, with the resulting improvement in body composition contributing neatly to shape-up, body building, muscle increase and augmentation of the dynamic strength of muscles (Column 1, lines 55-68, Column 2, lines 1-64).

Goldberg et al. disclose that an increase in muscle weight reflects an increase in protein and results from greater protein synthesis and reduced protein breakdown and that hypertrophy leads to greater maximal tension development (Abstract).

Goldberg disclose that insulin reduces overall protein breakdown in skeletal muscle (Abstract).

The prior art discloses a dietary supplement which comprises a soy formulation and preferably comprising 70-90%, by weight, protein, 1-5%, by weight fat, and 1-25%, carbohydrate which may in the form of a powder or liquid form. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method of supplementing the diet of an athlete or supplementing the diet of a human by administering a dietary supplement which mimics or enhances insulin activity to enhance muscle size and strength.

However, the prior art amply suggests the same as the combined teachings of the prior art discloses amounts of protein and carbohydrate which encompass or overlap the claimed amounts, the incorporation of L-arginine, whey protein, glutamine, carnitine, alanine and compounds which mimic or enhance insulin activity such as pinitol, in compositions which can be in the form of powders which can be mixed with a diluant such as water, which can be administered to athletes or immediately after exercise. Further, the prior art discloses that muscle hypertrophy can lead to greater maximal tension development and that muscle size is a reflection of increased protein synthesis and decreased protein breakdown. Furthermore, it is

disclosed that insulin reduces overall protein breakdown in skeletal muscle tissue. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the use of said composition would increase muscle mass and strength.

The examiner had duly considered the Applicant's arguments but deems them unpersuasive.

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, held that (1) it is error to look only the problem the patentee was trying to solve-any need or problem known in the filed of endeavor at the time of invention and addressed by the prior art can provide a reason for combining the elements in the manner claimed; (2) it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem-common sense teaches that familiar items may have obvious uses beyond their primary purposes, and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle (one of ordinary skill in the art is not automaton); (3) it is error to assume that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try". *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1397 (U.S. 2007). Further, the reason or motivation to modify the reference may often suggest what the inventor has done but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In *re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); In *re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991).

Ostlund disclose that both pinitol is used for treating conditions associated insulin resistance including complications arising from athletic activity and that inositol compounds improve insulin sensitivity. As such, said compounds meet the scope of the limitation "a compound which mimics or enhances insulin activity". The Applicant has questions about the phrase "complications arising from athletic activity or inactivity". The phrase provides the motivation to add said compounds. The Applicant's argument does not provide evidence that one of ordinary skill in the art would not be motivated to add the inositol compounds to exercise supplements based on the disclosure in Ostlund et al.. Further, since inositol compounds would be expected to enhance insulin activity, in view of the teachings of the prior art relative to the effects of insulin on skeletal muscle, one of ordinary skill in the art would expect that the combination of inositol and the like with protein would increase muscle mass and strength versus protein alone by inhibiting the breakdown of muscle protein.

The Applicant offers the Declaration of Dr. Marvin A. Heuer (6/15/2007) as evidence of synergistic activity. However, the declarant does not appear to have performed any comparative study with the closest prior art and merely cites to an abstract of another. An affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. In re Burckel, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979). The test only compared Nitro-Tech® to whey protein and placebo, however, the claims encompass and claims and the prior art discloses the use of other proteins and other nutritional ingredients. A review of the Nitro-Tech® ingredient list clearly shows that the alleged evidence of unexpected activity is not commensurate in scope of the claims in that the claims considerably larger in scope than the tested composition. See In re Clemens, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Claims were directed to a process for removing

corrosion at "elevated temperatures" using a certain ion exchange resin (with the exception of claim 8 which recited a temperature in excess of 100C). Appellant demonstrated unexpected results via comparative tests with the prior art ion exchange resin at 110C and 130C. The court affirmed the rejection of claims 1-7 and 9-10 because the term "elevated temperatures" encompassed temperatures as low as 60C where the prior art ion exchange resin was known to perform well. The rejection of claim 8, directed to a temperature in excess of 100C, was reversed.). See also *In re Peterson*, 315 F.3d 1325, 1329-31, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003) (data showing improved alloy strength with the addition of 2% rhenium did not evidence unexpected results for the entire claimed range of about 1-3% rhenium); *In re Grasselli*, 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983) (Claims were directed to certain catalysts containing an alkali metal. Evidence presented to rebut an obviousness rejection compared catalysts containing sodium with the prior art. The court held this evidence insufficient to rebut the prima facie case because experiments limited to sodium were not commensurate in scope with the claims). Further, the test does not show synergy. In order to show synergy one would have had to test the mimetic alone also in order to see if the effect of the combination was greater than the sum of the effect of mimetic alone and whey protein alone. However, since as indicated above, the tested composition contains an extensive number of other ingredients which may also effect muscle growth and strength, even this hypothetical test would not have been sufficient to show synergy which is commensurate in scope with the claims. As such, the declaration is not sufficient to provide evidence of unexpected activity much less synergistic activity.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
June 24, 2007


Johann R. Richter
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